

## Food and Drug Administration, HHS

## § 178.3400

(b) The following corrosion inhibitors or adjuvants are used in amounts not to exceed those reasonably required to accomplish the intended physical or technical effect:

(1) Corrosion inhibitors (active ingredients) used in packaging materials for the packaging of steel or tinplate or articles fabricated therefrom:

| List of substances   | Limitations |
|--|-------------|
| Dicyclohexylamine and its salts of fatty acids derived from animal or vegetable oil.<br>Dicyclohexylamine nitrite.<br>Morpholine and its salts of fatty acids derived from animal or vegetable oils. |             |

(2) Adjuvants employed in the application and use of corrosion inhibitors:

| List of substances | Limitations |
|--------------------|-------------|
| Propylene glycol.  |             |

### § 178.3400 Emulsifiers and/or surface-active agents.

The substances listed in paragraph (c) of this section may be safely used as

emulsifiers and/or surface-active agents in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect; and the quantity that may become a component of food as a result of such use shall not be intended to, nor in fact, accomplish any physical or technical effect in the food itself.

(b) The use as an emulsifier and/or surface-active agent in any substance or article that is the subject of a regulation in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

(c) List of substances:

| List of substances  | Limitations  |
|---|--|
| $\alpha$ -Alkyl-, $\alpha$ -alkenyl-, and $\alpha$ -alkylaryl- <i>omega</i> -hydroxypoly(oxyethylene) mixture consisting of 30 weight pct of $\alpha$ -(2,4,6-trisobutylphenyl)- <i>omega</i> -hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 7 moles and 70 weight pct of a 1:1 weight ratio mixture of $\alpha$ -(Z)-9-octadecenyl- <i>omega</i> -hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 18 moles and $\alpha$ -alkyl( $C_{16}$ - $C_{18}$ )- <i>omega</i> -hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 18 moles. | For use only at levels not to exceed 0.5 pct by weight of coatings complying with § 175.320 of this chapter and limited to use as an emulsifier for polyhydric alcohol diesters used as provided in § 178.3770(b). The weight of the finished coating shall not exceed 2 milligrams per square inch of food-contact surface.   |
| <i>n</i> -Alkylbenzenesulfonic acid (alkyl group consisting of not less than 95 percent $C_{10}$ to $C_{16}$ ) and its ammonium, calcium, magnesium, potassium, and sodium salts.   | For use only as emulsifiers and/or surface active agents as components of nonfood articles complying with §§ 175.300, 175.320, 175.365, 175.380, 176.170, 176.180, 177.1010, 177.1200, 177.1210, 177.1630, 177.2600, and 177.2800 of this chapter and § 178.3120.  |
| Alkyl mono- and disulfonic acids, sodium salts (produced from <i>n</i> -alkanes in the range of $C_{10}$ - $C_{18}$ with not less than 50 percent $C_{14}$ - $C_{16}$ ).  | For use only:<br>1. As provided in § 176.170 of this chapter.<br>2. At levels not to exceed 2 percent by weight of polyvinyl chloride and/or vinyl chloride copolymers complying with § 177.1980 of this chapter.<br>3. As emulsifiers in vinylidene chloride copolymer or homopolymer coatings at levels not to exceed a total of 2.6 percent by weight of coating solids. The finished polymer contacts food only of the Types I, II, III, IV, V, VIA, VIB, VII, VIII, and IX as identified in table 1 of § 176.170(c) of this chapter, and limited to conditions of use E, F, and G described in table 2 of § 176.170 of this chapter.<br>4. As emulsifiers and/or surface-active agents at levels not to exceed 3.0 percent by weight of polystyrene or rubber-modified polystyrene complying with § 177.1640(c) of this chapter under conditions of use B through H described in table 2 of § 176.170(c) of this chapter. |
| $\alpha$ -Alkyl- <i>omega</i> -hydroxypoly(oxyethylene) produced by condensation of 1 mole of $C_{11}$ - $C_{15}$ straight-chain randomly substituted secondary alcohols with an average of 7–20 moles of ethylene oxide.   |  |

| List of substances   | Limitations   |
|--|---|
| <i>alpha</i> Olefin sulfonate [alkyl group is in the range of C <sub>10</sub> –C <sub>18</sub> with not less than 50 percent C <sub>14</sub> –C <sub>16</sub> ], ammonium, calcium, magnesium, potassium, and sodium salts.  | For use only:<br>1. In acrylonitrile-butadiene copolymers identified in § 177.2600(c)(4)(i) of this chapter.<br>2. At levels not to exceed 1 percent by weight of acrylic coatings complying with § 175.300(b)(3)(xx) of this chapter and having a maximum thickness of 0.051 millimeter (0.002 inch). The finished polymers contact food only of the Types V, VIII, and IX as identified in table 1 of § 176.170(c) of this chapter.<br>3. At levels not to exceed 2 percent by weight of vinyl chloride copolymer coatings having a maximum thickness of 0.051 millimeter (0.002 inch) and complying with § 175.300(b)(3)(xv) of this chapter. The finished polymers contact food only of the Types V, VIII, and IX as identified in table 1 of § 176.170(c) of this chapter.<br>4. As provided in § 175.105 of this chapter. |
| <i>Alpha</i> -sulfo- <i>omega</i> -(dodecyloxy)poly(oxyethylene) ammonium salt (CAS Reg. No. 30174–67–5).  | For use only as an emulsifier at levels not to exceed 0.3 percent by weight of styrene-butadiene copolymer coatings for paper and paperboard complying with § 176.170 of this chapter.  |
| Ammonium salt of epoxidized oleic acid, produced from epoxidized oleic acid (predominantly dihydroxystearic and acetoxyhydroxystearic acids) meeting the following specifications: Acid number 160–180, saponification number 210–235, iodine number 2–15, and epoxy groups 0–0.4 percent.   | For use only:<br>1. As a polymerization emulsifier at levels not to exceed 1.5 pct by weight of vinyl chloride polymers used as components of nonfood articles complying with §§ 175.105, 175.300, 176.170, 176.180, and 177.1210 of this chapter. Such vinyl chloride polymers are limited to polyvinyl chloride and/or vinyl chloride copolymers complying with § 177.1980 of this chapter.<br>2. As a polymerization emulsifier at levels not to exceed 1.5 pct by weight of vinyl chloride-vinyl acetate copolymers used as components of nonfood articles complying with §§ 175.105, 175.300, 176.170, 176.180, and 177.1210 of this chapter.  |
| Butanedioic acid, sulfo-1,4-di-(C <sub>10</sub> –C <sub>11</sub> alkyl) ester, ammonium salt (also known as butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt [CAS Reg. No. 144093–88–9])..  | For use as a surface active agent as provided in §§ 175.105, 175.125, 176.170, and 176.180 of this chapter.   |
| <i>α</i> -Di- <i>sec</i> -butylphenyl- <i>omega</i> -hydroxypoly(oxyethylene) produced by the condensation of 1 mole of di- <i>sec</i> -butylphenol with an average of 4–14 or 30–50 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range 4–14 or 30–50; <i>sec</i> -butyl groups are predominantly (90 percent or more) <i>o</i> -, <i>p</i> -substituents. |   |
| Disodium 4-isodecyl sulfosuccinate (CAS Reg. No. 37294–49–8).  | For use only as an emulsifier at levels not to exceed 5 percent by weight of polymers intended for use in coatings.   |
| <i>α</i> -Dodecyl- <i>omega</i> -hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 103–111 and that are produced by the esterification of the condensation product of 1 mole of <i>n</i> -dodecyl alcohol with 4–4.5 moles of ethylene oxide.  |   |
| <i>α</i> -( <i>p</i> -Dodecylphenyl)- <i>omega</i> -hydroxypoly (oxyethylene) produced by the condensation of 1 mole of dodecylphenol (dodecyl group is a propylene tetramer isomer) with an average of 4–14 or 30–50 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range 4–14 or 30–50.  |   |
| Naphthalene sulfonic acid-formaldehyde condensate, sodium salt (CAS Reg. No. 9084–06–4).   | For use only:<br>1. At levels not to exceed 10 micrograms/in <sup>2</sup> (0.16 mg/dm <sup>2</sup> ) in vinylidene chloride copolymer or homopolymer coatings applied to films of propylene polymers complying with § 177.1520 of this chapter.<br>2. At levels not to exceed 14 micrograms/in <sup>2</sup> (0.21 mg/dm <sup>2</sup> ) in vinylidene chloride copolymer or homopolymer coatings applied to films of polyethylene phthalate polymers complying with § 177.1630 of this chapter.  |

| List of substances  | Limitations   |
|---|---|
| <p><math>\alpha</math>-(<i>p</i>-nonylphenyl)-<i>omega</i>-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 49–59 and that are produced by the esterification of <i>a</i>-(<i>p</i>-nonylphenyl)-<i>omega</i>-hydroxypoly (oxyethylene) complying with the identity prescribed in § 178.3400(c) and having an average poly(oxyethylene) content of 5.5–6.5 moles.</p> <p><math>\alpha</math>-(<i>p</i>-Nonylphenyl)-<i>omega</i>-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 62–72 and that are produced by the esterification of <math>\alpha</math>-(<i>p</i>-nonylphenyl)-<i>omega</i>-hydroxypoly (oxyethylene) complying with the identity prescribed in § 178.3400(c) and having an average poly(oxyethylene) content of 9–10 moles.</p> <p><math>\alpha</math>-(<i>p</i>-Nonylphenyl)-<i>omega</i>-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 98–110 and that are produced by the esterification of <math>\alpha</math>-(<i>p</i>-nonylphenyl)-<i>omega</i>-hydroxypoly (oxyethylene) complying with the identity prescribed in § 178.3400(c) and having an average poly(oxyethylene) content of 45–55 moles.</p> <p><math>\alpha</math>-(<i>p</i>-Nonylphenyl)-<i>omega</i>-hydroxypoly (oxyethylene) produced by the condensation of 1 mole of nonylphenol (nonyl group is a propylene trimer isomer) with an average of 4–14 or 30–50 moles of ethylene oxide: if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range 4–14 or 30–50.</p> <p><math>\alpha</math>-(<i>p</i>-Nonylphenyl)-<i>omega</i>-hydroxypoly (oxyethylene) sulfate, ammonium or sodium salt: the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content average 4 moles.</p> <p>Polyethyleneglycol alkyl(C<sub>10</sub>–C<sub>12</sub>) ether sulfosuccinate, disodium salt (CAS Reg. No. 68954–91–6).</p> <p>Poly[(methylene-<i>p</i>-nonylphenoxy) poly(oxypropylene)(4–12 moles) propanol] of minimum molecular weight 3500.</p> <p>Poly(oxypropylene) (45–48 moles) block polymer with poly(oxyethylene). The finished block polymers meet the following specifications: Average molecular weight 11,000–18,000; hydroxyl number 6.2–10.2; cloud point above 100 °C. for 10 pct solution.</p> <p>Polysorbate 20 (polyoxyethylene (20) sorbitan monolaurate) meeting the following specifications: Saponification number 40–50, acid number 0–2, hydroxyl number 60–108, oxyethylene content 70–74 pct.</p> <p>Polysorbate 40 (polyoxyethylene (20) sorbitan monopalmitate) meeting the following specifications: Saponification number 41–52, oxyethylene content 66–70.5 pct.</p> <p>Polysorbate 60 conforming to the identity prescribed in § 172.836 of this chapter.</p> <p>Polysorbate 65 conforming to the identity prescribed in § 172.838 of this chapter.</p> <p>Polysorbate 80 conforming to the identity prescribed in § 172.840 of this chapter.</p> <p>Polysorbate 85 (polyoxyethylene (20) sorbitan trioleate) meeting the following specifications: Saponification number 80–95, oxyethylene content 46–50 percent.</p> <p>Sodium 1,4-dicyclohexyl sulfosuccinate.</p> <p>Sodium 1,4-diethyl sulfosuccinate.</p> <p>Sodium 1,4-diisobutyl sulfosuccinate.</p> <p>Sodium dioctyl sulfosuccinate.</p> <p>Sodium 1,4-dipentyl sulfosuccinate.</p> <p>Sodium 1,4-ditridecyl sulfosuccinate.</p> <p>Sodium lauryl sulfate.</p> <p>Sodium monoalkylphenoxybenzenedisulfonate and sodium dialkylphenoxybenzenedisulfonate mixtures containing not less than 70 pct of the monoalkylated product where the alkyl group is C<sub>8</sub>–C<sub>16</sub>.</p> <p>Sorbitan monolaurate meeting the following specifications. Saponification number 153–170; and hydroxyl number 330–360.</p> | <p>For use only at levels not to exceed 5 percent by weight of total monomers used in the emulsion polymerization of polyvinyl acetate, acrylic, and vinyl/acrylic polymers intended for use as coatings for paper and paperboard.</p> <p>For use in coatings at levels not to exceed 1 mg per square foot of food-contact surface.</p> <p>For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings. Such polyolefin film and polyolefin coatings shall have an average thickness not to exceed 0.005 inch and shall be limited to use in contact with foods that have a pH above 5.0 and that contain no more than 8 pct of alcohol.</p> |

| List of substances  | Limitations   |
|---|---|
| <p>Sorbitan monooleate meeting the following specifications: Saponification number 145–160, hydroxyl number 193–210.</p> <p>Sorbitan monopalmitate meeting the following specifications: Saponification No. 140–150; and hydroxyl No. 275–305.</p> <p>Sorbitan monostearate conforming to the identity prescribed in § 172.842 of this chapter.</p> <p>Sorbitan trioleate meeting the following specifications: Saponification No. 170–190; and hydroxyl No. 55–70.</p> <p>Sorbitan tristearate meeting the following specifications: Saponification No. 176–188; and hydroxyl No. 66–80.</p> <p>Sulfosuccinic acid 4-ester with polyethylene glycol dodecyl ether, disodium salt (CAS Reg. No. 39354–45–5).</p> <p>Sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt (alcohol moiety produced by condensation of 1 mole nonylphenol and an average of 9–10 moles of ethylene oxide) (CAS Reg. No. 9040–38–4).</p> <p><math>\alpha</math>-[<i>p</i>-(1,1,3,3-Tetramethylbutyl)phenyl] <i>omega</i>-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of <i>p</i>-(1,1,3,3-tetramethylbutyl) phenol with an average of 4–14 or 30–40 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range 4–14 or 30–50.</p> <p>Tetrasodium <i>N</i>-(1,2-dicarboxyethyl)-<i>N</i>-octadecyl-sulfosuccinate</p> <p><math>\alpha</math>-Tridecyl-<i>omega</i>-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 75–85 and that are produced by the esterification of the condensation product of one mole of “oxo” process tridecyl alcohol with 5.5–6.5 moles of ethylene oxide.</p> <p><math>\alpha</math>-Tridecyl-<i>omega</i>-hydroxypoly (oxyethyl-ene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 58–70 and that are produced by the esterification of the condensation product of one mole of “oxo” process tridecyl alcohol with 9–10 moles of ethylene oxide.</p> | <p>For use only at levels not to exceed 5 percent by weight of total monomers used in the emulsion polymerization of polyvinyl acetate, acrylic, and vinyl/acrylic polymers intended for use as coatings for paper and paperboard.</p> <p>For use only at levels not to exceed 5 percent by weight of the total coating monomers used in the emulsion polymerization of polyvinyl acetate and vinyl-acrylate copolymers intended for use as coatings for paper and paperboard.</p> <p>For use only as a polymerization emulsifier for resins applied to tea-bag material.</p> |

(d) The provisions of this section are not applicable to emulsifiers and/or surface-active agents listed in § 175.105(c)(5) of this chapter and used in food-packaging adhesives complying with § 175.105 of this chapter.

[42 FR 14609, Mar. 15, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 178.3400, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

#### § 178.3450 Esters of stearic and palmitic acids.

The ester stearyl palmitate or palmityl stearate or mixtures thereof may be safely used as adjuvants in food-packaging materials when used in accordance with the following prescribed conditions:

(a) They are used or intended for use as plasticizers or lubricants in poly-

styrene intended for use in contact with food.

(b) They are added to the formulated polymer prior to extrusion.

(c) The quantity used shall not exceed that required to accomplish the intended technical effect.

#### § 178.3480 Fatty alcohols, synthetic.

Synthetic fatty alcohols may be safely used as components of articles intended for use in contact with food, and in synthesizing food additives and other substances permitted for use as components of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) The food additive consists of fatty alcohols meeting the specifications and definition prescribed in § 172.864 of this chapter, except as provided in paragraph (c) of this section.